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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,479	03/31/2004	David W. Moskowitz	60019190-1038	7392

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EXAMINER	
GRAFFEO, MICHEL	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/820,479	MOSKOWITZ, DAVID W.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 8-15 (claims 14 and 15 beyond the elected specie of claims 6-7)* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III, claims 6-7 and losartan as the angiotensin receptor blocker during a telephone conversation on 30 May 2006 is acknowledged. Applicant's election of Group III with traverse in the reply filed on 6 June 2006 is also acknowledged. The traversal is on the ground(s) that the inventions of Groups I-IV are closely related and have a common utility. This is not found persuasive because the standard for a proper restriction is not based on the relatedness of the inventions, without more, or whether or not they have a common utility. As noted in the restriction requirement, the Groups are directed to different compounds, different indications, different patient populations etc. and therefore have different designs, modes of operations, functions and effects. Claims 1-5 and 8-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

Status of Action

Claims 6-7 and 14-15 (claims 14-15 are examined to the extent of the elected species) are examined.

Claim Rejections - 35 USC § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-7 and 14-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification and the prior art combined, while being enabling for a method of treating symptoms related to viral infections which is considered an embodiment within the scope of the treatment of viral infections, does not reasonably provide enablement for the treatment of a viral infection via a treatment that targets the viral agent itself. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

To the extent that losartan targets a viral agent, there is no support in the Specification. Neither the Specification nor the prior art explain or connect the viral targeting and subsequent treatment of a viral agent with losartan. At the time of filing the instant Application, viral treatments were still limited in nature. See under Treatment and Prognosis in: Viral Infections: Infectins of the Brain and Spinal Cord: Merck Manual Home Edition. http://www.merck.com/mmhe/print/sec06/ch089/ch089d.html. Retrieved 3 June 2006, which teaches that for other than a small number of viruses no specific treatment is available and that current treatments involve relieving symptoms and when necessary supporting life. Also, see US PreGrant Publication No. 2004/0259934 to Olsen et al. which describes the mechanism by which losartan treats SARS.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-7 and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US PreGrant Publication No. 2004/0259934 to Olsen et al.

Olsen et al. teach a method of treating SARS with Losartan in paragraph 118:

> viramidine. In another aspect of this embodiment, the other agent active against the SARS virus is an angiotensin II receptor blocker (e.g., losartan). In still another aspect of this embodiment, the other agent active against the SARS virus is 2'-C-methylcytidine, or a pharmaceutically acceptable salt thereof.

And further wherein Olsen teaches that angiotensin receptor blockers can act to down modulate the host's immune response to SARS and thereby decrease mortality due to SARS (see paragraph 157 citing: "GenoMed Reaffirms Potential Utility of Sartans for SARS", Apr. 28, 2003, http://www.prnewswire.com; "GenoMed Announces Potential Therapy for SARS", Apr. 25, 2003, http://www.prnewswire.com).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12 June 2006
MG

A. H. Marschel 6/12/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER